

## **REMARKS/ARGUMENTS**

### **1. *Status of the Claims***

In this Amendment, claims 1, 3, 5-10, 12-13, 21, 23-30 and 37-40 are canceled. Claims 43-48 are added. Claims 2, 22, 31-34, 36, and 41-42 are amended. Claims 22-29 and 35-39 were withdrawn from consideration by the Examiner. The amendment to claims 22 and 36 limits the subject matter of claims 22, 35 and 36 to the elected invention. Accordingly, claims 2, 22, 31-36, and 41-48 are pending and under consideration with entry of this Amendment.

### **2. *Support for the Amendments***

Support for the amendments to the claims can be found throughout the specification, the drawings, and the claims as originally drafted. The amendments generally incorporate the limitations of dependent claims or merely include sequence information instead of referring to figures in the application. The Examiner will note that the rat sequences depicted in Figure 10B differ somewhat from the human sequences set forth in the sequence listing, therefore necessitating the nucleotide changes referred to in the claims. New claim 47 finds support on lines 25-28 of page 17 of the specification. No new matter is introduced by this Amendment.

### **3. *Claim Objections***

The Examiner withdrew claims 22-29 and 35-39 from consideration because the claims are allegedly directed to a different invention and were introduced after the first Office Action. Applicants respectfully request that the Examiner consider recombining the withdrawn claims with the claims under examination because the art, enablement and written description issues do not appear to be significantly different from those under consideration and therefore does not amount to an undue burden for the Examiner.

**4. *Claim objections***

Claims 30-34 and 40-42 were objected to as dependent from an allegedly non-elected base claim. As amended, the claims at issue are either canceled or have been amended to dependent from a claim reciting elected subject matter.

Claims 31-34, 41 and 42 were also objected to because the claims referred to figures rather than sequence identification numbers. As amended, the claims refer to sequence identification numbers.

In view of the amendments, Applicants request withdrawal of the objections.

**5. *Non-statutory subject matter rejection***

Claims 9, 10 and 40-42 were rejected as allegedly directed to non-statutory subject matter. Specifically, the Examiner noted that without the modifier "isolated", the claims could be interpreted to read on human beings. As amended, the claims include the word "isolated," thereby overcoming the rejection. Accordingly, Applicants respectfully request withdrawal of the rejection.

**6. *Rejections under 35 U.S.C. § 112***

**A. *Claim 3: Written description***

Claim 3 was rejected under 35 U.S.C. § 112, first paragraph as allegedly not complying with the written description requirement. The Examiner argued that the claims as drafted did not require hybridization to SEQ ID NO:1 because of the way the claim was drafted. Moreover, the Examiner argued that the specification did not provide a limiting definition of "highly stringent" hybridization conditions. The Examiner indicated that amending the claims to include the hybridization conditions set forth on page 17, line 27 would overcome the rejection.

Applicants respectfully traverse the rejection. Claim 3 is canceled with this Amendment, thereby rendering the rejection moot.

New claim 22 reflects much of the subject matter of claim 3. Claim 22 requires hybridization to SEQ ID NO:1, rather than a sequence comprising SEQ ID NO:1, and the claims

include the hybridization conditions provided on page 27 of the specification. Accordingly, Applicants believe the claim is allowable.

***B. Claims 9, 10 and 40-42: Enablement***

Claims 9, 10 and 40-42 were rejected as not enabled for their full scope. Specifically, the Examiner argued that while the claims were enabled for isolated host cells, the claims as drafted encompass cells within transgenic animals.

Applicants traverse the rejection and assert that at most only routine experimentation is necessary to generate transgenic animals comprising the recited genetic constructs. However, in the interests of expediting prosecution, all pending claims directed to host cells include the word "isolated." Accordingly, Applicants respectfully request withdrawal of the rejection.

***7. Rejections under 35 U.S.C. § 102***

Claims 1, 3, 5, 7, and 21 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Blank *et al.*, as evidenced by NCBI Accession No. S76011. Moreover, claims 1, 3-12 and 21 were also rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Shimizu *et al.* as evidenced by Blank *et al.* Applicants respectfully traverse the rejection.

Each of the rejected claims are canceled in this Amendment, thereby rendering the rejection moot. Moreover, each of the currently pending claims either include subject matter that was not rejected (e.g., claim 2) or includes sequences comprising "sufficient sequence from the first introns of the SM  $\alpha$ -A gene to confer smooth muscle cell-specific expression *in vivo*." Neither reference cited by the Examiner teaches or suggests that intronic sequence plays a role in promoter regulation. Accordingly, Applicants respectfully request withdrawal of the rejections.

Appl. No. 09/807,757  
Amdt. dated December 16, 2003  
Reply to Office Action of October 1, 2003

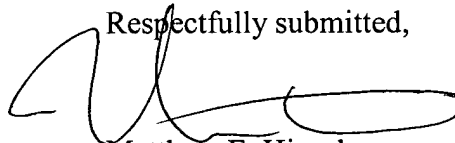
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**CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Matthew E. Hinsch', is written over the typed name.

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